

IN RESPONSE, PLEASE
REFER TO: M120424

May 2, 2012

MEMORANDUM TO: R. W. Borchardt
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS – BRIEFING ON PART 35 MEDICAL
EVENT DEFINITIONS – PERMANENT IMPLANT
BRACHYTHERAPY, 9:00 A.M., TUESDAY, APRIL 24, 2012,
COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT
NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC
ATTENDANCE)

The Commission was briefed by representatives of the medical community and the NRC staff on proposed regulatory changes to the Medical Events definitions for permanent implant brachytherapy programs. The medical community representatives were: James Welsh, M.D., Radiation Oncologist, Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee Chair on Medical Event Reporting for Prostate Brachytherapy; Anthony Zietman, M.D., Chairman, Board of Directors, American Society for Radiation Oncology; W. Robert Lee, M.D., American Brachytherapy Society; Chris Timmerman, Senior Nuclear Engineer, Wisconsin Department of State Health Services, Radiation Protection Section, and Organization of Agreement States; and Laura Weil, Patients' Rights Advocate, ACMUI.

The staff should provide a CA note within 3 weeks of the SRM to inform the Commission's vote on SECY-12-0053 with possible options to clarify Medical Event reporting for permanent implant brachytherapy under the existing rule, ahead of the current schedule for the expanded 10 CFR Part 35 rulemaking. The CA note should cover options for addressing the challenges that exist with the current medical event reporting including separating the rule on the definition of medical event for permanent brachytherapy from the comprehensive Part 35 rule, use of orders, and issuance of guidance. The staff should also provide its views regarding the compatibility category for 10 CFR 35.3045 reporting requirements.

(EDO)

(SECY Suspense:

5/23/12)

Further staff guidance will be provided in the Staff Requirements Memorandum for SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs."

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)
PDR